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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/641,701	08/21/2000	Yoshinao Kojima	195870USO	8831

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EXAMINER

PROUTY, REBECCA E

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/04/2003

68

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/641,701

Applicant(s)

Kojima et al.

Examiner

Rebecca Prouty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 13, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-35 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12, 18, 24, and 30 is/are allowed.
- 6) ☒ Claim(s) 13-17, 19-23, 25-29, and 31-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Claims 1-11 have been canceled. Claims 12-35 are still at issue and are present for examination.

Applicants' arguments filed on 8-13-03, paper No. 17, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim 14 is objected to because of the following informalities: the word "of" should be inserted before SEQ ID NO:2 in line 2. Appropriate correction is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 14, 20, 26 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Tang et al. (WO 01/57190). The rejection is explained in the previous Office Action.

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The declaration filed on 8-13-03 under 37 CFR 1.131 has been considered but is ineffective to overcome the Tang et al. reference.

The evidence submitted is insufficient to establish a reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the Tang et al. reference as does not provide evidence that the CD77 encoding nucleic acid described in Seikagaku 71(8): 704 is that of the current claims. Furthermore, it fails to state that the experiments described in Seikagaku 71(8): 704 were performed in a in this country or a NAFTA or WTO member country and is not signed by inventor Yoshinao Kojima.

Claims 14-17, 20-23, 26-29, and 32-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Clausen et al. (US-PGPUB 2003/0138807).

Clausen et al. teach a polynucleotide (SEQ ID NO: 10) consisting of the full length coding region of the gene encoding human GB3 synthase and the encoded protein (SEQ ID NO:11) as well as vectors and host cells comprising said polynucleotide and methods of expressing the encoded protein. SEQ ID NO:10 was first disclosed in US priority application 60/182,037 (filed 2/11/00) and is 100% identical to nucleotides 134-1192 of SEQ ID NO:1 with the exception of a single degenerate mismatch at

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position 1036. Clausen et al. further teach several allelic variants of SEQ ID NO:10 in Table 1 which include the substitution of the C at position 903 of SEQ ID NO:10 (equivalent to position 1036 of SEQ ID NO:1 of the instant application) with a G. Individuals (for example donors #183, #168 and #300 of Table II of Clausen et al.) with this polymorphism encode nucleic acids 100% identical to nucleotides 134-1192 of SEQ ID NO:1. Clausen et further inserted a nucleic acid identical to nucleotides 134-1192 of SEQ ID NO:1 into an insect cell and Namalwa cell expression vectors and expressed the encoded protein (see particularly construct #67 of Examples 3 and 4). Thus Clausen et al. anticipate all of the instant claims.

The declaration filed on 8-13-03 under 37 CFR 1.131 has been considered but is ineffective to overcome the Clausen et al. reference for all the reasons noted above with regard to the Tang et al. reference. Furthermore, the Clausen et al. reference is a U.S. patent application publication of a pending application that claims the rejected invention. An affidavit or declaration is inappropriate under 37 CFR 1.131(a) when the reference is claiming the same patentable invention, see MPEP § 2306. If the reference and this application are not commonly owned, the reference can only be overcome by establishing priority of invention through interference proceedings. See MPEP Chapter

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2300 for information on initiating interference proceedings. If the reference and this application are commonly owned, the patent may be disqualified as prior art by an affidavit or declaration under 37 CFR 1.130. See MPEP § 718.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13, 19, 25, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tang et al. (WO 01/57190) or Clausen et al. (US-PGPUB 2003/0138807) in view of Tsein et al. (US Patent 5,625,048).

Tang et al. and Clausen et al. are discussed above. SEQ ID NO:2482 of Tang et al. meets all limitation of Claim 13 except it is only 1111 nucleotides in length. Similarly SEQ ID NO:10 and

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the polymorphic variant thereof of construct #67 of Clausen et al. meets all limitation of Claim 13 except it is only 1059 nucleotides in length. Thus Tang et al. and Clausen et al. do not specifically disclose a polynucleotide of about 1975 nucleotides in length as recited in Claim 13. However Tang et al. and Clausen et al. do disclose that the polynucleotides disclosed can be fused to other polynucleotides to produce fusion proteins (see page 32 of Tang et al. and paragraph [0070] of Clausen et al.).

Tsein et al. teach polynucleotides encoding *Aequorea* GFP which is a commonly used fusion partner in the art as it can be easily tracked and quantified as well as polynucleotides encoding such fusion polypeptides. (see particularly column 6 and Claims 15-17 and 23-25). Tsein et al. further teach the inclusion of sequences encoding additional small peptide sequences such as a His tag and/or a flexible peptide spacer between the sequences encoding GFP and the peptide of interest. The polynucleotide sequence encoding GFP is 716 nucleotides in length.

Therefore, it would have been obvious to one of skill in the art to fuse the sequence encoding SEQ ID NO:2482 of Tang et al. or SEQ ID NO:10 or the polymorphic variant thereof of construct #67 of Clausen et al. to the sequence encoding GFP and optionally

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including nucleotide sequences encoding a histidine tag, an oligopeptide spacer and/or a promoter sequence for the expression of the fusion protein. All such constructs would be within the scope of "about 1975" nucleotides in length and would clearly hybridize under even highly stringent conditions to SEQ ID NO:1 and encode a Gb3 synthase. One would have been motivated to do so for the ease of detecting and purifying the protein encoded by SEQ ID NO:2482 of Tang et al. or SEQ ID NO:10 or the polymorphic variant thereof of construct #67 of Clausen et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (703) 308-4000. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Rebecca Prouty
Primary Examiner
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